

U.S. SERIAL NO. 08/765,108
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However, to facilitate prosecution, the claims have been limited to a nucleic acid encoding the scavenger receptor protein.

The rejection as to the scope of the claims to the antibody appears to be based on a misreading of the claims. The reference to "selectively" is to the scavenger receptor protein; not the antibody.

It is difficult to understand the rejection as to the claims which have been interpreted as including more than what is enabled on the basis that the specification does not enable everything. To the extent the examiner has rejected the claims on the basis that the scavenger receptor BI protein is not defined other than functionally, the limitation that the molecule is encoded by a nucleotide molecule hybridizing to SEQ ID Nos. 3 and 7 have been incorporated into the claims. The data on page 27 indicates that this defines a distinct protein. In combination, the functional and sequence limitations define a unique protein. No other protein having this binding specificity has been identified. See, for example, the discussion at page 11 and data on binding at pages 26-31 of the specification. It is well established that the requirement is that one of ordinary skill in the art be able to make that which is claimed - the specification enables one of skill in the art to make and use at least two, and assertedly many more than two, type BI scavenger receptor protein and antibodies thereto. As described in the application, once one type BI scavenger receptor protein encoding molecule was obtained, it was routine to isolate a second molecule. As described in the application, it was routine to make and use both monoclonal and polyclonal antibodies to the type BI scavenger receptor protein. Numerous court decisions have held that one need not enable every single possible variation or embodiment.

With regard to the claims relating to compounds which inhibit binding, the application does indeed show numerous binding studies in which competitive inhibition and alteration of binding is demonstrated. See, for example, Figures 3A and 3B; 4A and 4B; 5; 7A-E. These actual working example clearly demonstrate that such assays are routine and would require absolutely no undue experimentation. The Examiner's attention is drawn to the claims which are directed to **methods**, not the products identified by the methods.

Claims 44-50 were rejected as indefinite for lacking enough steps, and for failing to adequately define the term "scavenger receptor protein". As discussed above, the scavenger receptor protein is defined by the amended claims as a type BI scavenger receptor protein, encoded by a molecule hybridizing to the disclosed sequences and possessing unique binding activities.

Claim 12 has been amended to recite liver and lung cells.

The term "sequence" has been replaced with "molecule".

Claim 14 is clear; alternative language is fully acceptable as definite under §112.

The "consisting essentially of" language has been deleted from claim 15.

The term "the" in claim 19 has been replaced with "a".

Claims 21 and 22 have been amended to recite a composition.

Claims 45-47 have been amended to define methods rather than an assay.

Claim 46 has been amended to delete "naturally occurring or synthetic" since both are encompassed by the term "compounds".

Claim 47 has been amended to recite the compounds whose binding to the scavenger receptor typ BI is altered.

Claims 11 to 22 recite that the claimed molecule is **isolated**; such a molecule does not exist in nature.

Rejections under 35 U.S.C. §103

Claims 9, 10, 13, 14, 18, 19, 21 and 22 were rejected under 35 U.S.C. §103 as obvious over Calvo, et al. J. Biol. Chem. 268(25), 18929-18935 (September 5, 1993). These rejections are respectfully traversed.

Calvo, et al. reported isolation of a cDNA encoding a member of the CD36 family. The protein was not physically isolated nor was the cloned DNA expressed on the surface of cells and shown to be functional, although a small piece (the carboxyl terminal region including residues 365-409) was expressed as a chimeric protein (page 18930). The function of the protein was not known, although its resemblance to CD36 was recognized based on the predicted similarities in structure and the authors speculated that "on the basis of its structural homology to CD36 that CLA-1 could act as a receptor for extracellular products" (page 18934).

It is well established that reduction to practice does not occur merely upon reporting of the existence of a material in the literature; constructive reduction to practice can only occur upon filing of a patent application. To prove a reduction to practice, an applicant must show that "the embodiment relied upon as evidence of priority actually worked for its intended purpose." *Holmwood v. Sugavanam* 948 F.2d 1236, 1238, 20 U.S.P.Q.2d (BNA) 1712 (Fed. Cir. 1991), quoting *Newkirk v. Lulejian*, 825 F.2d 1581, 1582, 3 U.S.P.Q.2d (BNA) 1793, 1794 (Fed. Cir. 1987).

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There can also be no constructive reduction to practice, since it is well established that constructive reduction to practice only occurs upon filing of a patent application. *Popeil Bros., Inc. v. Schick Electric, Inc.*, 356 F. Supp. 240, 244, 176 U.S.P.Q. (BNA) 101 (N.D. Ill 1972), *aff'd*, 181 U.S.P.Q. (BNA) 482 (7th Cir. 1974).

Accordingly, at most Calvo, et al. discloses a DNA encoding a CD36 protein of human origin, with unknown function.

Enclosed is a copy of the Declaration under 37 C.F.R. §1.131 submitted in the parent application, U.S. Serial No. 08/265,428 filed June 23, 1994, which demonstrates that a cDNA and encoded protein defined by the claims in issue was reduced to practice prior to the publication of Calvo, et al. Applicants cloned the gene, they expressed the protein, and they characterized the protein and showed its function, **prior to** Calvo's publication date.

37 C.F.R. § 1.131 states, in pertinent part,

(a)(1) When any claim of an application . . . is rejected under 35 U.S.C. 102 (a) or (e), or 35 U.S.C. 103 based on . . . reference to . . . a printed publication, the inventor of the subject matter of the rejected claim . . . may submit an appropriate oath or declaration to overcome the . . . publication. The oath or declaration must include facts showing a completion of the invention in this country or in a NAFTA or WTO member country before . . . the date of the printed publication.

* * *

(b) The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the

invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice

Through a Rule 131 declaration, an applicant attempts to show that references relied upon the examiner, and other references, are removed as prior art because applicant had already actually reduced the invention to practice before the effective date of the references (e.g., the date of publication). Filing a declaration in this situation is called "swearing behind" the reference. The applicant need only provide evidence that reasonably gives rise to an inference that the invention was completed before the reference date, in order to constitute a prima facie showing. No corroboration is required since the application process is ex parte. A Rule 131 affidavit is sufficient when it demonstrates that the applicant has prior "possession" of that part of the invention disclosed by the reference, as is the case when a reference discloses a species falling within a claim to its genus. See Donald S. Chisum, **Patents** § 3.08[1][b] (Matthew Bender & Co. 1996). Possession in this context is shown by demonstrating conception, reduction to practice, and diligence--each as normally required in determining the date of invention. See In re Mulder, 716 F.2d 1542 (Fed. Cir. 1983).

In In re Stempel, 241 F.2d 755 (C.C.P.A. 1957), the court held that applicant's affidavit under Rule 131 was not required to show priority with respect to the claimed genus, but only to the species disclosed by the cited reference, in order to remove that reference as prior art. The claims, both genus and species were drawn to chemical compounds. Stempel overcame the anticipation rejection by showing reduction to practice, prior to the effective date of the reference, of a species of the invention within the generic claims.

In In re Tanczyn, 347 F.2d 830 (C.C.P.A. 1965), the court qualified In re Stempel, stating that the Stempel doctrine did not apply to *partial* possession of the invention, as distinguished from *total* possession of a species within a genus claim. The Tanczyn application "did not involve a genus-species relationship." Id. at 833. The court reaffirmed Stempel in its application to rejections under 35 U.S.C. § 102(a), but held in reference to § 103 rejections,

"[w]e never intended . . . to authorize the overcoming of references by affidavits showing that the applicant had invented, prior to the reference date, a part, some parts, or even a combination of parts, used to create an embodiment of his claimed invention, where the part or parts are not within the scope of the claims being sought, as the species of Stempel shown by the reference was within his generic claims

It is not sufficient to show in a Rule 131 affidavit that an invention is wholly outside of that being claimed was made prior to the reference date. Such fact is irrelevant."

In In re Clarke, 356 F.2d 987 (C.C.P.A. 1966), the court extended the Stempel doctrine to the situation at issue in this application, that is where the applicant's Rule 131 affidavit shows possession that is *not* of the entire invention nor of the part of the invention disclosed by the reference. The Clarke court held that the affidavit is sufficient to remove a reference where the applicant demonstrates possession of such "invention" as to make the entire claimed invention or the reference part obvious to one of ordinary skill in the art. The court stated,

"[i]n an appropriate case an applicant should not be prevented from obtaining a patent to an invention where a compound described in a reference would have been obvious

to one of ordinary skill in the art in view of what the affiant proves was completed with respect to the invention prior to the effective date of the reference. . . . Thus, we think that in an appropriate case a single species could be sufficient to antedate indirectly a different species of a reference."

The CCPA also has phrased the rule, "[w]hen that species of the generic invention which has been completed prior to the effective date of the reference would make obvious to one of ordinary skill in the art the species disclosed in the reference, the reference may be said to have been 'indirectly antedated.'" In re Schaub, 537 F.2d 509, 512 (C.C.P.A. 1976) (quoting In re Ranier, 390 F.2d 771, 773-74 (C.C.P.A. 1968)). The Schaub court stated that "[a]ppellants have made a prima facie case that the compound of the reference is obvious from the compounds which they have made prior to the date of the reference. Appellants' compound III is the next higher homolog of the reference compound II, . . ." Id. at 512-13.

There is little, if any, Federal Circuit case law on point. However, the rule established in In re Clarke apparently remains valid, as one somewhat recent, "unpublished" (i.e. not citable as precedent) case seems to indicate. In In re Rozmus, 928 F.2d 412, 1991 WL 17232 (Fed. Cir.), the court stated that "[a]lthough Rozmus' [Rule 131] declaration showed reduction to practice of only a species of the generic invention, that alone is not fatal to his claim. A declaration proving a species is also sufficient to show possession of 'variations and adaptations which would, at the same time, be obvious to one skilled in the art.'" (quoting In re Spiller, 500 F.2d 1170, 1178 n.5 (CCPA 1974)).

Other cases discussing priority but which do not involve Rule 131 have stated, "[p]riority as to a genus may . . . be shown by prior invention of a single species, but the

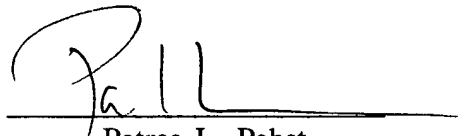
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genus will not be patentable to an applicant unless he has generic support therefor." In re Zletz, 893 F.2d 319, 323 (Fed. Cir. 1989); *see also* Hoffman v. Schoenwald 15 U.S.P.Q.2d 1512, 1514 (Bd. Pat. App. & Int'f 1990) ("Conception of a species within the genus constitutes conception of the genus for priority of invention purposes.").

Applicants have demonstrated that they cloned and expressed the hamster gene encoding the claimed SR-BI proteins, and that the gene hybridizes to the murine gene, prior to publication by Calvo. Accordingly, Applicants conceived of and reduced to practice the claimed invention prior to Calvo. Therefore, the Declaration under 37 C.F.R. §1.131 should conclusively remove Calvo as a reference, and the claims found patentable to Appellants.

Allowance of all claims 1-15, 19-22, and 44-50, as amended, is earnestly solicited.

Respectfully submitted,

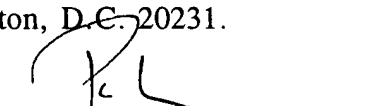

Patrea L. Pabst
Reg. No. 31,284

Date: December 29, 1997
ARNALL GOLDEN & GREGORY LLP
2800 One Atlantic Center
1201 W. Peachtree Street
Atlanta, GA 30309-3450
(404) 873-8794

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner of Patents, Washington, D.C. 20231.

Date: December 29, 1997


Patrea L. Pabst